Rep. Joseph R. Pitts
Opening Statement
Energy and Commerce Committee

Markup of H.R. 4795, Promoting New Manufacturing Act; H.R. 4801, to require the Secretary of Energy to prepare a report on the impact of thermal insulation on both energy and water use for potable hot water; H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act; H.R. 4709, the Ensuring Patient Access and Effective Drug Enforcement Act; and H.R. 4631, the Combating Autism Reauthorization Act

June 9 and 10, 2014

Thank you, Mr. Chairman.

I'm very pleased that the three, bipartisan bills the Health Subcommittee marked up on May 28 are being brought before the Full Committee for consideration.

For the sake of time, I will limit my remarks to H.R. 4299, the Improving Regulatory Transparency for New Medical Therapies Act, which I and Ranking Member Pallone introduced on March 26th of this year.

H.R. 4299 seeks to improve the transparency and consistency of DEA's scheduling of new FDA-approved drugs under the Controlled Substances Act (CSA), and its registration process for manufacturing controlled substances for use in clinical trials. Ultimately, this will allow new and innovative treatments to get to patients who desperately need them faster.

It now takes, on average, well over a billion dollars and 14 years from the time a drug is discovered to the time of approval.

This Committee has taken steps to provide more transparency and consistency in the drug approval process through the Prescription Drug User Fee program and a commitment to review goals embedded in the PDUFA agreements.

However, drugs that contain substances that have not been previously marketed in the United States and that have abuse potential must also be scheduled under the CSA by the DEA before they can begin marketing their product.

But, under the CSA, there is no deadline for the DEA to make a scheduling decision, and the delays in DEA decisions have increased nearly five-fold since 2000.

This lack of predictability in the timing of DEA scheduling decisions leads to unnecessary uncertainty in the drug development process and needless delays in patients' access to new therapies.

H.R. 4299 simply requires DEA to issue an Interim Final Rule 45 days after it receives FDA's scheduling recommendation for a new drug, allowing patients access to new therapies 45 days after FDA approval.

The DEA would retain its authority to subsequently transfer the drug between schedules under the Section 201 of the CSA.

This bill also establishes a timeline for DEA to grant approval of manufacturers' applications to register controlled substances, not yet approved by FDA, to be used in clinical trials, allowing companies to properly plan clinical trial schedules for prospective new therapies.

This provision will get products to the market faster because innovators will be able to get clinical trials underway in a timely and predictable way; which is critical to drug developers and patients alike.

I urge support of all three bills, and I yield back.